FUJIFILM

FUJIFILM MEDICAL SYSTEMS USA, INC.

419 WEST AVENUE
STAMFORD, CT 06902
PHONE: 203-324-2000
TOLL-FREE: 800-431-1850
FAX: 203-353-0926

510(k) Summary

K 121674

Date Prepared: June 1, 2012

SEP 2 1 2012

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, Connecticut 06902
Telephone: (203) 602-3576
Facsimile: (203) 353-0296
Contact: Peter Altman

Device Name and Classification:

Product Name:	Aspire HD Plus and Aspire HD-s
Model Number:	FDR MS-2500 and FDR MS-2000
Classification Name:	Full-Field Digital Mammography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR 892.1715
Device Class:	Class II
Product Code:	MUE

Substantial Equivalence/Predicate Devices:

FUJIFILM Aspire HD (FDR MS-1000) (K110729)

The predicate and proposed devices have the same Indication For Use (IFU). All three devices generate digital mammographic images that are intended for screening and diagnosis of breast cancer and are intended for use in the same clinical applications as traditional screen-film mammography systems.

All systems employ the same digital amorphous selenium x-ray detector integrated into gantry (stand) based x-ray systems. The x-ray stand, tube and generator of the Aspire HD Plus and Aspire HD-s are essentially identical. Note that the Aspire HD's X-ray system was manufactured by Siemens, whereas the Aspire HD Plus and Aspire HD-s X-ray systems are manufactured by Fujifilm. The technological characteristics of the devices are similar as demonstrated by the comparison of imaging characteristics such as MTF, Noise Analysis, DQE, CNR, Phantom testing, etc. measured during non-clinical testing. Non-clinical testing was conducted in accordance with the FFDM 510(k) Guidance document covering Sensitometric Response, Spatial Resolution, Noise Analysis, Signal-to-Noise Ratio Transfer – DQE, Dynamic Range, Image Erasure and Fading, Repeated Exposure Test, AEC Performance, ACR MAP Phantom Testing, Contrast Detail Phantom Testing, Patient Radiation Dose Testing, and Breast Compression system Testing.

A clinical image attribute review was conducted by independent mammographic radiologists in accordance with the FFDM 510(k) Guidance document. The mammographic attributes of six (6) image sets per exposure mode of screening and diagnostic cases were reviewed concluding that the Aspire HD Plus provides sufficiently acceptable quality for mammographic use. Since the Aspire HD Plus and Aspire HD-s have exactly the same imaging geometry and components (detector, and X-ray system), the results of the image attribute review apply to both systems.

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Description of the Device:

The Aspire HD Plus and Aspire HD-s are integrated FFDM systems combining an X-ray system made by Fujifilm with Fujifilm's a-Se detector and Acquisition Workstation (AWS). The Aspire HD Plus and Aspire HD-s create digital mammography images by direct capture of x-ray energy using the a-Se detector. The detector is a Fujifilm design utilizing an exclusive dual layer a-Se scintillator with Direct Optical switching circuitry to acquire image data and transfer images to the AWS for automated post processing, technologist preview and QC, and subsequent transmission to hard copy printers, diagnostic workstations and archiving systems. The Aspire HD Plus and Aspire HD-s provide automated compression and three AEC modes.

The Aspire HD Acquisition Workstation (FDR 2000AWS) includes an off the shelf personal computer, the application software, Windows 7 Operating System, a 5megapixel portrait type monitor, and a hub. The hub transmits signals between the personal computer and control cabinet, and between the personal computer and exposure stand.

The AWS display primarily consists of three windows:

- Patient Information Input window
- Exposure Menu Selection window
- Study window.

The user may switch between these windows depending on the operation being performed. The X-ray control panel, which controls and observes the exposure stand, is always displayed in the lower part of each window. This allows setting the exposure conditions and confirming the radiation conditions on a single view.

Intended Use:

The Fujifilm Digital Mammography Systems, Aspire HD Plus (FDR MS-2500) and Aspire HD-s (FDR MS-2000), generate full-field digital mammography images that can, as other full-field digital mammography systems, be used for screening and diagnosis of breast cancer and are intended for use in the same clinical applications as traditional screen-film mammography systems.

Safety Information:

The Aspire HD Plus and Aspire HD-s introduce no new safety or efficacy issues other than those already identified with the predicate device. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the devices are of moderate concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and is consistent with the level of concern indicated in the "Class II Special Controls Guidance Document: Full-Field Digital Mammography System" document issued on: November 5, 2010.

Conclusion:

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject devices to be as safe and effective as the predicate device based upon the clinical and non-clinical data summarized above.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 21 2012

Mr. Peter Altman
Regulatory Consultant
FUJIFILM Medical Systems, USA Inc.
419 West Avenue
STAMFORD CT 06902

Re: K121674
Trade/Device Name: Aspire HD Plus (FDR MS-2500) and Aspire HD-s (FDR MS-2000)
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: September 21, 2012
Received: September 21, 2012

Dear Mr. Altman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121674

Device Name: __

Indications for Use:

The Fujifilm Digital Mammography Systems, Aspire HD Plus (FDR MS-2500) and Aspire HD-s (FDR MS-2000), generate full-field digital mammography images that can, as other full-field digital mammography systems, be used for screening and diagnosis of breast cancer and are intended for use in the same clinical applications as traditional screen-film mammography systems.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 121674